

# A Pilot Study of Dietary Nitrate Supplementation in Anaemic Patients

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## BACKGROUND

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Anaemia affects 60-90% of people with cancer. A lower haemoglobin (Hb) is associated with a worse quality of life. Erythropoietin treatment improves both Hb and quality of life but is associated with significant risk. Blood transfusions improve Hb but only have a short-term effect on quality of life.

Stored blood has a reduced NO bioavailability causing reduced vasodilation, reduced blood flow and oxygen delivery to muscles, and reduced exercise tolerance and muscle oxidative function.

Dietary nitrate supplementation has been shown to be of significant benefit in healthy individuals. It improves mitochondrial efficiency, reduces metabolic rate, increases blood flow to areas of the body requiring more oxygen, and reduces the effect of hypoxia on exercise capacity and muscle recovery.

Therefore, we hypothesise that dietary supplementation of anaemic patients with nitrate-rich beetroot juice (BR) will have similar beneficial effects, compared to nitrate-deplete beetroot juice (PL).

### Hypotheses

1. Dietary supplementation with Nitrate ameliorates the symptoms of chronic anaemia
2. Blood transfusions contain more nitrate scavengers than circulating blood, meaning patients receiving blood transfusions have an altered nitrate metabolism
3. Nitrate supplementation improves the following in anaemic patients:
  1. Cognitive function
  2. Muscular function and exercise tolerance
  3. Quality of life
  4. Thrombogenicity

### Aims

1. This pilot randomised control study is examining the feasibility of the recruitment of patients with cancer-related anaemia
2. Provide estimates of standard deviations in main outcome measures
3. Guide power calculations for a future study investigating whether nitrate supplementation is beneficial for anaemic patients

### Objectives

Objectives include analysis of ease of recruitment and study completion rates, estimation of standard deviations of main outcomes, quality of life data collection, analysis of exercise tolerance and related measures, refinement of measurements of S-Nitrosothiols, nitrate, and analysis of platelet aggregation.

## METHODS

This prospective randomised crossover study is recruiting patients with anaemia who attend the Royal Devon and Exeter Haematology and Oncology Departments. Participants attend The University of Exeter 4 times for quality of life assessment, blood pressure measurement, exercise physiology and Magnetic Resonance Spectroscopy (MRS) analysis.

They receive both BR and PL supplementation during their trial involvement as outlined below.



Visit 1 – exercise testing, blood tests and questionnaire



5 doses of active or inactivated supplement over 2 days



Visit 2 – exercise testing, blood tests and questionnaire



Six-twelve weeks later

Visit 3 – exercise testing, blood tests and questionnaire



5 doses whichever supplement not given before



Visit 4 – exercise testing, blood tests and questionnaire



## RESULTS

### RECRUITMENT

- 33 patients recruited so far (target 40)
- 4 withdrawals (2 due to patient ill health, 1 due to ill health of wife, one because of refusal by another trial)
- 21 patients have completed all 4 visits

### PATIENT DEMOGRAPHICS

- Age range 43 to 93 (mean 68)
- Mean Hb 110.9 g/l
- 19 males, 14 females

### DATA

Interim analysis of data will occur shortly when researchers are unblinded following completion of 1 more patient's visits. No further results regarding the hypotheses are available at present.

## CONCLUSIONS

This study is recruiting well and is easily meeting its targets. Most patients approached are keen to enrol. Interim analysis is about to commence.